

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:
State of Iowa v. Abbott Laboratories, et al.

Judge Patti B. Saris

**MEMORANDUM OF LAW IN SUPPORT OF CERTAIN
DEFENDANTS' MOTION TO DISMISS THE COMPLAINT**

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INTRODUCTION

Iowa has been an active participant in the state-federal Medicaid partnership for decades. Yet Iowa alleges that it “[o]nly recently . . . learned that the reported AWP’s often bear no relationship whatsoever to defendants’ true prices,” Compl. ¶ 72, and that “AWP is to be construed according to its plain meaning, *to wit*, it is supposed to represent an average of the actual prices charged by wholesalers and/or paid by providers to wholesalers,” Compl. ¶ 93.

Iowa’s claims of “recent” knowledge are belied by the public record. In a 1986 statute, the Iowa General Assembly directed the Iowa Department of Human Services (“DHS”) to change Medicaid reimbursement from an AWP-based system to one based upon actual acquisition costs. Using federal reports and independent analyses, DHS determined that AWP’s exceeded actual drug transaction costs. Over the ensuing two decades, the federal government continued to inform state Medicaid agencies, including DHS, that AWP’s were substantially higher than actual acquisition costs. Iowa’s claims of “recent” knowledge are contradicted by the public record.¹ Iowa’s true knowledge defeats any claim of falsity, deception, or fraud and the Complaint should be dismissed as a result.

Iowa also fails to plead adequately each of its causes of action, which include both claims relating to prices (such as AWP and/or WAC) reported to pricing compendia, and claims relating to the reporting of “Best Price” under the Medicaid Rebate Statute. Count I falls short because Iowa has no private right of action under the Medicaid Rebate Statute. Count II fails because Iowa has no right to sue manufacturers under the Medicaid Rebate Agreements.

¹ Certain public record materials have been included in Defendants’ Appendix for the Court’s judicial notice. While generally a court should only consider the complaint and documents affixed thereto for purposes of a motion to dismiss, an exception is made “for documents the authenticity of which are not disputed by the parties; for *official public records*; for documents central to plaintiffs’ claim; or for documents sufficiently referred to in the complaint.” *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33-34 (1st Cir. 2001) (emphasis added) (citations and internal quotation marks omitted).

Count III should be rejected because Iowa is not a “person” within the meaning of the Iowa Consumer Fraud Act, which protects consumers and not the State. Iowa does not seek damages on behalf of consumers. Count IV’s common law fraud claim is inadequate because elements of a fraud claim are not sufficiently pleaded. Count V fails because the State has not adequately alleged that Defendants were unjustly enriched. The Complaint’s various other allegations regarding federal upper limit (“FUL”), State Maximum Allowable Cost (“SMAC”), and Best Prices do not state proper claims.²

Finally, and in addition to all of the above inadequacies, the Complaint lacks the particularity required by Federal Rules of Civil Procedure 8(a) and 9(b).

BACKGROUND

I. Federal Medicaid Program³

Medicaid is a “grant-in-aid” program in which the federal and state governments jointly share expenses related to providing medical assistance to low-income and other qualified persons. *See* 42 U.S.C. § 1396 *et seq.* Most prescription drugs are covered under Medicaid, including those dispensed by pharmacies and those administered by physicians. The Centers for Medicare and Medicaid Services (“CMS”), formerly known as the Health Care Financing Administration (“HCFA”), oversees the Medicaid program at the federal level.

Federal law imposes certain aggregate upper limits on what state Medicaid agencies may pay for prescription drugs. *See* 42 C.F.R. § 447.500 (2008). Prior to 2007, for certain

² The Complaint also protests Defendants’ alleged misreporting of Wholesale Acquisition Cost (“WAC”). *See* Compl. ¶¶ 87-92. Since 2003, WAC has been statutorily defined as “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price.*” 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added).

³ In light of the Court’s familiarity with the essence of the federal Medicaid program, we briefly summarize the program here.

“multiple source” drugs, the federal government required that states pay no more, “in the aggregate,” than a reasonable dispensing fee, plus 150% of the published price for the least costly therapeutic equivalent that could be purchased by pharmacists in standard quantities. 42 C.F.R. § 447.332(b) (2006). This was known as the federal upper limit or FUL.⁴ For all other drugs, i.e., single source drugs or multiple source drugs for which no FUL had been established, the state was permitted to pay, “in the aggregate,” the lower of the estimated acquisition cost (“EAC”) of the drug (plus a reasonable dispensing fee) or the provider’s usual and customary charges to the general public. 42 C.F.R. § 447.331 (2006).

II. Iowa Medicaid Program

Iowa began its Medicaid program in 1967 with passage of the “Medical Assistance Act.”⁵ DHS has oversight responsibility.⁶ *See* Iowa Code § 249A.4 (2007). Persons eligible for Iowa Medicaid assistance include those who meet certain low income, disability, or other criteria. Iowa Code § 249A.3 (2007). The Iowa Medicaid program is funded 63.55% by the federal government. “A Plan for Iowa Medicaid Reform: Frequently Asked Questions,” <http://staffweb.legis.state.ia.us/lfb/medicaid/FAQ.pdf> (Mar. 30, 2005).

A. Iowa Medicaid Reimbursement, In General

The Medical Assistance Act states that Iowa Medicaid reimbursement should be “at a level as near as possible to actual costs and charges” after priority is given to efficient and cost-

⁴ FUL is now set at no more than 250% of the AMP for the least costly therapeutic equivalent. *See* 42 C.F.R. § 447.514 (2008). The United States District Court for the District of Columbia, however, has issued a preliminary injunction enjoining CMS from implementing the final rule concerning the definition of AMP. *Nat’l Ass’n of Chain Drug Stores v. Leavitt*, No. 07-02017 (D.D.C. filed Dec. 19, 2007).

⁵ The Medical Assistance Act was enacted as chapter 223 of the laws of the 62nd General Assembly. *See* 1967 Iowa Acts ch. 223 (Defendants’ Appendix Exhibit (“Defs. App. Ex.”) A). It is now codified at Iowa Code ch. 249A (2007).

⁶ Previously, the State Board of Social Welfare was responsible for administering Iowa’s Medicaid program. *See* 1967 Iowa Acts ch. 223, §§ 3, 5 (Defs. App. Ex. A).

effective delivery of health services, compliance with federal law and regulations, and the level of available state and federal appropriations. Iowa Code § 249A.4(9) (2007).

In many Iowa counties, certain Medicaid beneficiaries are required to obtain medical services through a managed health care provider, either a health maintenance organization (“HMO”) or a MediPASS doctor. *See generally* Iowa Admin. Code r. 441-88 (2008). HMOs are paid a monthly fee (capitation rate) for each enrolled recipient for the provision of covered medical services, regardless of whether those recipients receive medical care during that month. Iowa Admin. Code r. 441-88.1 (2008) (definition of “capitation rate”); *see also* Iowa Admin. Code r. 441-88.12(1) (2008).⁷ MediPASS is a gatekeeper system through which certain Medicaid recipients are assigned a primary care provider; recipients work through that provider to obtain Medicaid services. Iowa Admin. Code r. 441-88.41 (2008). Unlike the HMO program, MediPASS providers do not receive a capitated rate per Medicaid patient. Rather, as MediPASS “patient managers,” providers are paid a monthly fee of \$2.00 per enrolled recipient (up to a monthly maximum of \$3000) to cover patient management costs, including referrals. Iowa Admin. Code r. 441-88.50(1), (4) (2008). MediPASS providers are paid for other services in accordance with the usual Medicaid reimbursement rules. Iowa Admin. Code r. 441-88.50(1) (2008). The managed care option is available in 93 of Iowa’s 99 counties. “Iowa Medicaid

⁷ The Iowa Administrative Code does not clearly specify whether prescription drugs (both those that are obtained through retail pharmacies and those that are physician-administered) are covered under the capitated rate. *See generally* Iowa Admin. Code r. 441-88.5(2), (3) (2008). The template “Contract for Services” available at the Bureau of Managed Care and Clinical Services website (<http://www.ime.state.ia.us/docs/HMO-Contract-withTOC2007-2009.doc>) specifically states at section 4.2.3 that among the services not covered under the contract are “Prescription drugs dispensed by retail pharmacies.” Among the covered physician services are “inpatient visits” and “office visits,” as well as “miscellaneous services,” which include “injections.” Thus, physician-administered drugs may fall within the purview of the capitated rate, which could significantly impact the State’s claims.

Enterprise – Managed Care,” <http://www.ime.state.ia.us/ManagedCare/ManagedCareHome.html> (last visited Feb. 14, 2008).

B. Historical Iowa Medicaid Drug Reimbursement Methodology And Iowa’s Knowledge Regarding AWP’s

The term “average wholesale price” first appeared in Iowa regulations in 1983. *See* VI Iowa Admin. Bull. 741-44 (Dec. 7, 1983) (Defs. App. Ex. B). At that time, Medicaid reimbursement was set at the provider’s or pharmacy’s “usual, customary, and reasonable charge,”⁸ but for drugs where a “lower cost alternative equivalent product” was available, the lower cost alternative was to be dispensed (absent a waiver), and reimbursement was capped at the “average wholesale price of the lower cost alternative product dispensed,” or, if not dispensed, “at the upper level of the range of average wholesale prices of the equivalent products.” *Id.* at 742 (Item 3(a)).

In 1986, the Iowa legislature directed DHS to abandon an AWP-based system and adopt a system based on actual acquisition cost:

Beginning July 1, 1986, the professional fee for pharmacies shall continue to be reduced by five and twenty-one hundredths percent until the department establishes a new reimbursement system for drug products based on estimates of actual acquisition costs. The department shall establish by October 1, 1986, unless disapproved by the United States department of health and human services, a new reimbursement system for drug products based on estimates of actual acquisition costs derived from data obtained from the department’s survey of drug product costs and professional fees. The department shall adjust the maximum allowable professional fee to reflect the change in the reimbursement system from average wholesale price reimbursement to actual acquisition cost reimbursement.

1986 Iowa Acts ch. 1246, § 309(1)(d) (Defs. App. Ex. C).

⁸ This had been the reimbursement methodology since the inception of the Iowa Medicaid program.

In response to this directive, DHS redefined reimbursement to be the pharmacist's or provider's "usual, customary, and reasonable charge," but not to exceed "the average wholesale price of the drug less ten and fifty-nine hundredths percent (10.59%)," plus a dispensing fee. *See* Iowa Admin. Code r. 498-78.2(a) (1987) (Defs. App. Ex. D). Where a lower cost alternative product was available (and absent a waiver or a doctor's certification that a brand name was required), reimbursement was to be based on the AWP of that lower cost alternative minus 10.59% or, if not dispensed, at "the upper level of the range of average wholesale prices of the equivalent products" minus 10.59%. *Id.*

This change (from AWP to AWP minus 10.59%) was based upon information provided by the federal government and obtained through an independent study:

At the current time the state is paying pharmacists for drugs for Medicaid clients based on the average wholesale prices of the drugs. The United States Department of Health and Human Services, Office of Inspector General (DHHS, OIG) has determined that published wholesale prices are approximately sixteen percent (16%) higher than the prices actually paid by providers.⁹ States have been asked by DHHS, OIG to develop Medicaid drug pricing levels that more accurately reflect prices that pharmacists are paying for drug ingredients.

The General Assembly directed the Department to establish a new reimbursement system for drugs based on estimates of actual acquisition costs derived from data obtained from the Department's survey of drug product costs and professional fees. The Department was also directed to adjust the maximum professional fee to reflect the change in the reimbursement system from average wholesale price reimbursement. Beginning on the date the new reimbursement system is implemented, the professional fees are to be reduced by three and eighty-five hundredths percent (3.85%) rather than five and twenty-one hundredths percent (5.21%).

This amendment implements the changes mandated by DHHS, OIG and the General Assembly. A study conducted by a consultant from the University of Nebraska, School of Pharmacy, determined that the average wholesale reimbursement is ten and fifty-nine hundredths percent

⁹ This is a reference to the Health and Human Services Office of Inspector General's 1984 Report. *See infra* p. 9.

(10.59%) higher than the actual acquisition cost. Therefore, the average wholesale cost will be reduced by that percentage.

The percentage reduction averages \$1.23 per prescription. Therefore, the professional fee will be increased from \$3.78 to \$5.01.

IX Iowa Admin. Bull. 1249-50 (Jan. 14, 1987) (Defs. App. Ex. E). The 1986 Act and implementing regulations prove:

- Iowa was carefully considering the federal Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) reports related to drug reimbursement (including the 1984 Report) and therefore knew that AWP were not equal to actual acquisition costs;
- DHS conducted (or directed to be conducted) a “survey of drug product costs,” from which it obtained “estimates of actual acquisition costs”;
- DHS was informed by a study commissioned by the University of Nebraska, School of Pharmacy that AWP were, on average, 10.59% higher than actual acquisition cost;¹⁰ and
- Even though Iowa reduced reimbursement by 10.59%, it simultaneously raised the dispensing fee to compensate for the 10.59% price reduction. Iowa clearly understood the cross-subsidization of drug costs and dispensing fees.

Since 1987, Iowa has had access to even more detailed information explaining that AWP did not represent actual transaction prices and that the differences between these two numbers continued to grow. The public record – which explains that AWP substantially exceeded transaction costs – is unassailable. For example, in 2002, Iowa was informed that the averages of discounts off of AWP for non-FUL drugs were 21.84% for brand name drugs and 65.9% for generics. *See infra* pp. 10-11.

Iowa chose to continue its AWP-based Medicaid drug reimbursement system. *See* Compl. ¶¶ 69, 78. From 1987 to 2003, the EAC for “covered prescription drugs” was AWP

¹⁰ It is not yet clear why Iowa adopted the University of Nebraska’s 10.59% discount versus the HHS OIG’s 16% discount.

minus 10%.¹¹ From 2003 to June 2005, Iowa used an AWP minus 12% EAC methodology. *See* Iowa Admin. Code r. 441-79.1(8)(a), (b) (2004) (Defs. App. Ex. F). *But see* Compl. ¶ 78 (“From 1991 to 2005, Iowa defined EAC as AWP-10%.”).

C. Current Iowa Medicaid Drug Reimbursement Scheme

Iowa continues to use an AWP-based drug reimbursement scheme today. Since June 25, 2005, Iowa has reimbursed for generic drugs at the *lowest* of: (1) EAC; which is AWP minus 12%; (2) FUL; (3) SMAC; or (4) the provider’s usual and customary charge. Iowa Admin. Code r. 441-79.1(8)(a) (2008); Compl. ¶ 74. During the same time, Iowa has reimbursed providers for brand name drugs based on the *lowest* of: (1) EAC (AWP minus 12%) or (2) the provider’s usual and customary charge. Iowa Admin. Code r. 441-79.1(8)(b) (2008); Compl. ¶ 77.

D. Iowa’s Access To Drug Acquisition Cost Data

In addition to federal HHS OIG reports and other publicly available information, Iowa has had access to actual transaction prices for all Medicaid drug transactions. Providers and pharmacies enrolled in Iowa Medicaid must make drug acquisition cost information available to DHS. Iowa Admin. Code r. 441-79.1(8)(i)(1) (2008). This has been the case since at least November 2002. *See* XXV Iowa Admin. Bull. 361-63, § 79.1(8)(i) (Sept. 4, 2002) (Defs. App. Ex. G) (establishing requirement for provision of transaction records, effective November 1, 2002). Further, SMAC is determined, in part, based upon pharmacy “purchase records.” Iowa Admin. Code r. 441-79.1(8)(a)(3) (2008). Iowa Medicaid must have access to purchase records in order to perform the SMAC calculations.

¹¹ Iowa apparently changed EAC from AWP minus 10.59% to AWP minus 10% sometime between 1987 and 1991. *See* Compl. ¶¶ 69, 78.

MOTION TO DISMISS STANDARD

A court should grant a Rule 12(b)(6) motion to dismiss when the complaint fails to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). Courts need not credit “bald assertions” or “unsupportable conclusions” set forth in a complaint, *Banco Santander de P.R. v. Lopez-Stubbe (In re Colonial Mortgage Bankers Corp.)*, 324 F.3d 12, 15 (1st Cir. 2003) (citation and internal quotation marks omitted), and a court is “not required to accept as true legal conclusions within the complaint.” *Rodrigues v. Scotts Co.*, No. 07-10104-GAO, 2008 WL 251971, at *1 (D. Mass. Jan. 30, 2008). A motion to dismiss should be granted if a complaint does not include enough facts to state a claim for relief that is “plausible on its face.” *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007).

ARGUMENT

I. GOVERNMENT KNOWLEDGE CONCERNING PUBLISHED PRICES PRECLUDES THE STATE’S CLAIMS CONCERNING DEFENDANTS’ REPORTING OF PRICES TO THE PRICING COMPENDIA

The State bears the burden of alleging the absence of knowledge in order to maintain any claim premised upon falsity, deception, or fraud. However, Iowa has long known that AWP’s do not reflect the actual average prices charged by wholesalers to pharmacists and other providers.¹² As early as 1984, states were told not to rely on AWP as a proxy for EAC. The HHS OIG cautioned that “AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price.” HHS-OIG, *Changes to the Medicaid Prescription Drug Program Could Save Millions*, A-06-40216 at 3 (Sept. 1984) (Defs. App. Ex. H). Beginning in 1989, HCFA actually rejected proposed state Medicaid plans that relied upon undiscounted AWP as the proxy for the statutory EAC drug reimbursement rate

¹² It is unclear whether Iowa argues that AWP should have represented actual acquisition cost, or that Iowa knew AWP was not actual acquisition cost, but did not know of the extent of the difference. *Compare* Compl. ¶ 93 *with* Compl. ¶¶ 71, 72.

and refused to pay the federal share of Medicaid drug reimbursement for claims based on undiscounted AWP. *See, e.g., Louisiana v. U.S. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Ark. Dep't of Human Servs.*, No. 90-119, 1991 WL 634857 (HHS D.A.B. Aug. 22, 1991).

In 1990, Congress acted to reform Medicaid by providing the states with a lucrative rebate program. *See* Omnibus Budget Reconciliation Act of 1990, as amended, codified at 42 U.S.C. § 1396r-8(e). The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, requires states to include in their Medicaid plans drugs from those manufacturers that enter into formal Rebate Agreements with CMS. Manufacturers must submit to the federal government “average manufacturer price” (“AMP”) and “Best Price” (“BP”) for all covered drugs. AMP and BP are defined under the statute and are used to calculate unit rebate amounts (“URAs”). These URAs are then provided to the states, allowing the states to calculate the rebates due based on each state’s drug utilization.¹³

Independent of the rebate program, HHS pressed states to revise how they determine EAC. In 1996, HCFA asked HHS OIG to investigate disparities between AWP and actual acquisition costs. HHS OIG surveyed eleven states and determined that AWP exceeded pharmacy invoice prices: “brand name” drugs could be purchased at an average of 18.3% below AWP and “generic” drugs could be purchased at an average of 42.5% below AWP. HHS-OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs*, A-06-96-00030 at 4 (Apr. 1997) (Defs. App. Ex. I); HHS-OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-97-00011 at 4 (Aug. 1997) (Defs. App. Ex. J). By 2002, OIG’s estimate of the average discounts off of AWP

¹³ The same data permits the states to calculate the AMPs for non-innovator multiple source drugs, because the per-unit rebate is simply 11% of AMP. 42 U.S.C. § 1396r-8(c)(3). The State thus need only divide the per-unit rebate by 11% to determine the AMP.

available to pharmacies rose to 21.84% for brand name drugs, and 65.9% for generics. HHS-OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products*, A-06-00-00023 at 3 (Aug. 2001) (Defs. App. Ex. K); HHS-OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053 at 3 (Mar. 2002) (Defs. App. Ex. L). Follow-up analysis determined that: (1) for single source innovator drugs, pharmacies purchased the drugs at an average discount of 17.2% below AWP; (2) for all drugs without FULs, the average pharmacy discount was 27.2% below AWP; (3) for multiple source drugs without FULs, the average pharmacy discount was 44.2% below AWP; and (4) for multiple source drugs with FULs, the average pharmacy discount was 72.1% below AWP. HHS-OIG, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041 at 4 (Sept. 2002) (Defs. App. Ex. M). Not only were these reports publicly available, but HHS OIG recommended that these reports be shared directly with the state Medicaid agencies, and CMS agreed to do so. *See, e.g., id.* at 10 (“In response to the recommendations in our draft report, CMS agreed to share our report with the states.”).

This Court has ruled that “[b]y the mid-1990’s, information about the existence of mega-spreads began to seep into the marketplace.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40 (D. Mass. 2007). This evidence, all of which was readily available to Iowa, included:

- The 1984 HHS OIG Report, discussed above, finding that AWP is not an adequate estimate of the prices providers pay for drugs because “AWP represents a list price and does not reflect several types of discounts . . . or free goods that do not appear on the pharmacists’ invoices” (citing DX 1039 at 10,206) (Defs. App. Ex. H);
- A 1996 HHS OIG Report, on physician-administered drugs again concluding that AWP is not a reliable indicator of the cost of drugs to providers and finding

spreads of up to 144% (citing DX 1062) (Defs. App. Ex. N);

- A June 10, 1996 *Barron's* article, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?*, describing AWP as “Ain’t What’s Paid” and concluding that providers pay as much as 60%-90% below AWP (citing DX 2641) (Defs. App. Ex. O);
- A 1997 Report of the House Budget Committee, stating that “the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs [which is based on AWP] ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs” (citing DX 1071 at 1354) (Defs. App. Ex. P);
- A 1997 radio address of President Clinton, in which he referred to AWP as a “sticker price” and added: “Sometimes the waste and abuses aren’t even illegal; they’re just embedded in the practices of the system . . . [T]hese overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for drugs.” (citing DX 1074 at 2033-34) (Defs. App. Ex. Q);
- A 1999 Report of Donna Shalala, the Secretary of HHS, to Congress, in which she emphasized the HHS OIG conclusion in a series of reports that “drugs can be obtained at a much lower cost than the AWP” and that AWP bore “no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace” (citing DX 1080 at 1-2, 8) (Defs. App. Ex. R).

Id. at 40-42, 76-78.

This Court has already held that by August of 1997,¹⁴ information was widely available demonstrating that AWP-based reimbursement did not accurately reflect acquisition costs, *id.* at 78-79, and that “[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General,” *id.* at 41. The public record discussed above, and the actions of Iowa’s own legislature and DHS, show that Iowa was aware that AWP did not accurately reflect acquisition costs as early as 1986.

In light of the public record, the State simply cannot maintain claims premised on AWP not representing actual acquisition costs (or even being within 10% or 12% of actual

¹⁴ The Balanced Budget Act was signed into law in August 1997.

acquisition costs). For example, to state a claim under the Iowa Consumer Fraud Act (Count III), the State must prove specific facts establishing a misleading or deceptive act or practice. *See generally* Iowa Code § 714.16 (2007); *State ex rel. Miller v. Hydro Mag, Ltd.*, 436 N.W.2d 617 (Iowa 1989). Since no Iowa or federal statute or regulation defines the term “AWP,” the State cannot demonstrate that AWP’s were deceptive or misleading without reference to the State’s understanding.

The State faces even more difficulty with its common law fraud claim (Count IV), where it must prove not only a deceptive act, but reliance and intent. *Cornell v. Wunschel*, 408 N.W.2d 369, 374 (Iowa 1987); *see also McGough v. Gabus*, 526 N.W.2d 328, 331 (Iowa 1995). The State’s unjust enrichment claim (Count V) is also dependent on a demonstration of fraud; the factual basis for this claim as articulated in the Complaint is simply a reiteration of the prior allegations. *See* Compl. ¶¶ 663-666. Here, again, Iowa’s knowledge is highly relevant.

Finally, Iowa bears the burden of proving damages. *Data Documents, Inc. v. Pottawattamie County*, 604 N.W.2d 611, 616 (Iowa 2000). Evidence of the State’s knowledge is relevant for proof of damages, as well as to show that the State failed to mitigate damages.

II. IOWA FAILS TO STATE CLAIMS UPON WHICH RELIEF CAN BE GRANTED

A. Count I Fails Because The State Has No Implied Right Of Action Under 42 U.S.C. § 1396r-8

The first two Counts of the Complaint do not concern the reporting of pricing information, such as AWP and/or WAC, to the pricing compendia, but instead purport to allege violations of the Medicaid Rebate Statute with respect to “Best Price” reporting. The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, authorizes drug manufacturers to enter into Rebate Agreements with CMS to pay rebates to states for agreed-upon outpatient drugs. The Rebate Agreement requires a manufacturer to submit to the federal government the AMP and BP for

each of its drugs. 42 U.S.C. § 1396r-8(b)(3)(A)(i). CMS relays quarterly URAs to each state, which allows the state to use its utilization data to calculate quarterly Medicaid rebates anticipated from the drug manufacturers. Sample Rebate Agreement, Section I(n) (Compl. Ex. E); 42 U.S.C. § 1396r-8(b)(1)(A).

Count I asserts a cause of action under the Rebate Statute against single source and brand name innovator manufacturers. The State alleges that these Defendants reported false Best Prices, which resulted in lower rebates paid to Iowa. This Court has consistently rejected claims that the Rebate Statute provides a right of action to a non-federal party. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 326 (D. Mass. 2005) (“*Mylan Labs.*”); *see also City of New York v. Abbott Labs.*, No. 04-cv-06054, 2007 WL 1051642 (D. Mass. Apr. 2, 2007) (“*Consol. NY Counties*”); *County of Suffolk v. Abbott Labs.*, 339 F. Supp. 2d 165, 177 (D. Mass. 2004).

To allow a private right of action to enforce a federal law, the Court must find legislative intent to create a private right and a private remedy. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) (“*Sandoval*”). In *Mylan Labs.*, this Court held that the Commonwealth of Massachusetts failed “to point to any provisions [under 42 U.S.C. § 1396r-8] demonstrating a Congressional intent to create a private *remedy* for the state which would allow the state to obtain penalties for the provision of false information.” 357 F. Supp. 2d at 325-26 (emphasis added). Individual states also have no remedy under the Rebate Statute because it expressly grants the Secretary of HHS the power to impose penalties. *Id.* at 326 (citing *Sandoval*, 532 U.S. at 290) (“the express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others”). Thus, like similar claims in other cases before this Court, Count I is not legally viable and should be dismissed.

B. Count II Fails Because The State Has No Enforceable Right To Sue Manufacturers Under The Medicaid Rebate Agreements

Count II fails because the State has no right to sue manufacturers under the Medicaid Rebate Agreements. The Rebate Statute grants states enforcement rights against specific participants in the Medicaid system – such as managed care organizations and community care providers – but not against manufacturers. 42 U.S.C. § 1396t(j); 42 U.S.C. § 1396u-2(e)(1). The fact that Congress granted states enforcement rights against some Medicaid participants, while omitting manufacturers, reinforces the conclusion that Congress intentionally reserved to HHS the enforcement of manufacturers’ obligations under the Rebate Agreements. Allowing Iowa to sue under the Rebate Agreements would create an “end-run” around the Medicaid statute’s reservation to HHS of enforcement authority against manufacturers. *See Davis v. United Air Lines, Inc.*, 575 F. Supp. 677, 680 (E.D.N.Y. 1983) (holding that where a comprehensive administrative scheme provides remedies, to infer a private right of action is inconsistent with the underlying purpose of the legislative scheme).

Defendants acknowledge that in *Mylan Labs.*, this Court allowed the Commonwealth of Massachusetts’ breach of contract claim with respect to the Rebate Agreements. Defendants respectfully disagree with the Court’s decision and ask that the Court reconsider its prior analysis, particularly in light of the unique status of the Rebate Agreements as government contracts.

Iowa asserts that it is a third-party beneficiary under the Rebate Agreements. Compl. ¶ 112. Under federal common law,¹⁵ a third-party beneficiary may enforce a commercial contract when (1) a “recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties,” and (2) “the circumstances indicate that the promisee

¹⁵ The Sample Rebate Agreement, Section IX(e) (Compl. Ex. E), provides that the Rebate Agreement “shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.”

intends to give the beneficiary the benefit of the promised performance.” Restatement (Second) of Contracts § 302 (1981); *accord Davis*, 575 F. Supp. at 680.

However, a more stringent third-party beneficiary test applies when, as here, one of the parties to a contract is the government or a governmental agency and the contract is for the benefit of the public at large:

When a contract is with a government entity, a more stringent test applies: Parties that benefit . . . are generally assumed to be incidental beneficiaries, and may not enforce the contract absent a clear intent to the contrary. The contract must establish not only an intent to confer a benefit, but also an intention . . . to grant [the third-party] enforceable rights.

Kremen v. Cohen, 337 F.3d 1024, 1029 (9th Cir. 2003) (alterations in original) (citation and internal quotation marks omitted); *see also Maniere v. United States*, 31 Fed. Cl. 410, 418 (1994) (“To entitle one to sue as a third-party beneficiary of a contract to which he is not a party, *the contract must reflect* the intent not merely to benefit the third-party but also to give him the direct right to compensation or to enforce that right against the promisor.” (citation omitted)).

The purpose of Medicaid is to provide medical assistance to low-income and other qualified persons. *See* 42 U.S.C. § 1396 *et seq.* Manufacturers enter into Rebate Agreements so that federal matching funds may be made available for the manufacturers’ covered outpatient drugs. 42 U.S.C. § 1396r-8(a)(1). Because the Rebate Agreements are between manufacturers and a government agency to provide a public benefit, Iowa must show intent by both HHS and the manufacturers to confer a benefit on the State and to permit the State to sue manufacturers to enforce the Rebate Agreements.

To determine the contracting parties’ intent under a contract, a court must look to the text of the agreement and the context in which the agreement was made. *Pub. Serv. Co. v. Hudson Light & Power Dep’t*, 938 F.2d 338, 342 (1st Cir. 1991); Restatement (Second) of Contracts § 302(1)(b) (1981). The Rebate Agreements do not suggest that Congress intended to

grant states enforceable rights against manufacturers. Sections IV, V, and VI contain the various enforcement mechanisms. *See* Sample Rebate Agreement (Compl. Ex. E). None of these provisions permits states to sue manufacturers. The Rebate Statute itself provides further context for the Rebate Agreement. As discussed above, the Rebate Statute never suggests that Congress intended to confer a right on states to sue manufacturers. The Rebate Statute and the Rebate Agreements grant the Secretary of HHS discretion to enforce the available penalty mechanisms against manufacturers. 42 U.S.C. § 1396r-8(b)(3)(B)-(C); Sample Rebate Agreement, Section IV (Compl. Ex. E). Iowa should not be permitted to sue manufacturers under the Rebate Agreements.

C. Count III Fails To State A Claim Under The Iowa Consumer Fraud Act Because The Iowa Consumer Fraud Act Is Designed To Protect Consumers, Not The State

1. Iowa Is Not A “Person” Within The Meaning Of The Iowa Consumer Fraud Act

Following Counts I and II, the Complaint attempts to allege claims concerning the defendants’ reporting of pricing information, such as AWP’s and/or WAC’s, to the pricing compendia. Count III purports to assert a claim under the Iowa Consumer Fraud Act (“CFA”).

As an initial matter, Iowa and its agencies are not “persons” under the CFA, so Iowa cannot bring a claim under the CFA on behalf of itself or DHS. Section 2 of the CFA provides:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a *person* has in fact been misled, deceived, or damaged, is an unlawful practice.

Iowa Code § 714.16(2)(a) (2007) (emphasis added).

Section 7 of the CFA provides:

A civil action pursuant to this section shall be by equitable proceedings. If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any *person* in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section.

Iowa Code § 714.16(7) (2007) (emphasis added).

While the Attorney General has the authority to bring a CFA case and to seek injunctive relief to stop prohibited practices or unlawful conduct, the Attorney General can only seek monetary judgments to “restore to any *person* in interest any moneys or property, real or personal.” *Id.* (emphasis added). Thus, while the Attorney General is authorized to seek the return of “moneys or property,” this authority is limited to instances when the Attorney General will restore the money or property at issue to a “person.”

The State, however, is not a “person.” A generic Iowa code provision concerning guidelines for the construction of statutes defines “person” as follows: “*Unless otherwise provided by law, ‘person’ means individual, corporation, limited liability company, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.*” Iowa Code § 4.1(20) (2007) (emphasis added). This generic statutory definition does not apply here, however, because the CFA separately defines “person” as including “any natural person or the person’s legal representative, [a] partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust

thereof.” Iowa Code § 714.16(1)(j) (2007). This definition explicitly does not include the State or any other governmental entity, including a state agency like DHS.

The inclusion of governmental entities in the general definition of “person” in Iowa Code § 4.1(20) (2007) demonstrates that the *exclusion* of the State and its agencies from the definition of “person” in the CFA, Iowa Code § 714.16(1)(j) (2007), was an intentional omission. Principles of statutory construction prohibit a court from altering the plain and unambiguous meaning of a term, particularly when the legislature has provided a definition. *Carolán v. Hill*, 553 N.W.2d 882, 887-88 (Iowa 1996) (“We cannot, under the guise of construction, enlarge or otherwise change the terms of the statute as the legislature adopted it.”); *Iowa Comprehensive Petrol. Underground Storage Tank Fund Bd. v. Mobil Oil Corp.*, 606 N.W.2d 359, 363 (Iowa 2000); *see also In re Marriage of Wessels*, 542 N.W.2d 486, 491 (Iowa 1995) (holding that intent is expressed by inclusion as well as omission); *Lenertz v. Mun. Court*, 219 N.W.2d 513, 516 (Iowa 1974) (holding “the express mention of one thing implies the exclusion of others”). Because the Iowa legislature has provided a detailed and exhaustive definition of the term “person” in the CFA that does not include the State, the State must be excluded from the definition of “person.” To hold otherwise would negate the express intent of the legislature to exclude the State. *See Carolán*, 553 N.W.2d at 887.

The Iowa CFA was patterned upon the Illinois Consumer Fraud and Deceptive Business Practices Act (“CFDBPA”). *See Hydro Mag*, 436 N.W.2d at 621; *see also Cassady v. Wheeler*, 224 N.W.2d 649, 652 (Iowa 1974). While Iowa courts do not appear to have addressed the issue, Defendants’ interpretation of the CFA’s definition of “person” is consistent with the

Illinois Supreme Court's interpretation of the Illinois CFDBPA.¹⁶ The Illinois Supreme Court has held that the term "person" as used in the Illinois CFDBPA does not include governmental agencies. *See Bd. of Educ. v. A, C & S, Inc.*, 546 N.E.2d 580, 598-99 (Ill. 1989) (holding that school districts are not included in the definition of "person" and therefore may not bring an action under Section 10a of the Illinois CFDBPA); *see also Du Page Aviation Corp. v. Du Page Airport Auth.*, 594 N.E.2d 1334, 1342 (Ill. App. Ct. 1992) (holding that "the [Du Page Airport] Authority is a municipal corporation, does not fall within the definition of 'person' in the [Illinois CFDBPA], and is therefore not subject to suit under the Act"). Given that the Iowa CFA is patterned on the Illinois CFDBPA, it is reasonable to conclude that the State is also not a person under the CFA, and thus cannot sue or recover damages under the CFA.

2. *Iowa Is Not A "Consumer" Within The Meaning Of The Consumer Fraud Act*

In addition, Iowa cannot bring a claim under the CFA on behalf of itself, or a State agency, because it is not a "consumer" within the meaning of the CFA. While the CFA does not define the term "consumer," the Illinois CFDBPA does, and that definition does not include the State or State agencies. 815 Ill. Comp. Stat. 505/1(e) (2007) ("The term 'consumer' means any person who purchases or contracts for the purchase of merchandise not for resale in the ordinary course of his trade or business but for his use or that of a member of his household."). Other authority makes clear that the term "consumer" refers only to individuals and natural persons and does not include the State or State agencies. *See, e.g.,* U.C.C. § 2-103(1)(c) (2003 rev.)

¹⁶ In 1975, the Illinois CFDBPA was amended to permit private rights of action. While the Iowa CFA does not allow for a private action like its Illinois counterpart, the Iowa CFA and the Illinois CFDBPA have essentially identical definitions of "person." According to the Illinois CFDBPA, "[t]he term 'person' includes any natural person or his legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof." 815 Ill. Comp. Stat. 505/1(c) (2007).

(“‘Consumer’ means an individual who buys or contracts to buy goods that, at the time of contracting, are intended by the individual to be used primarily for personal, family, or household purposes.”); U.C.C. § 2-103 cmt. (2003 rev.) (“A ‘consumer’ is a natural person who enters into a transaction for a purpose typically associated with consumers – *i.e.*, a personal, family or household purpose.”); Ga. Code Ann. § 10-1-392(a)(2) (2007) (“‘Consumer’ means a natural person.”); Black’s Law Dictionary 335 (8th ed. 2004) (Consumer means “[a] person who buys goods or services for personal, family, or household use, with no intention of resale; a natural person who uses products for personal rather than business purposes.”).

The “unlawful practices” prohibited by the CFA are cataloged in Iowa Code § 714.16(2)(a) (2007). The “unlawful practices” the State alleges here are “deception” and “unfair practices.” Compl. ¶ 653. Both “deception” and “unfair practices” must affect consumers to support a CFA violation. The CFA defines “deception” as “an act or practice which has the tendency or capacity to mislead a substantial number of *consumers* as to a material fact or facts.” Iowa Code § 714.16(1)(f) (2007) (emphasis added). “Unfair practice” is “an act or practice which causes substantial, unavoidable injury to *consumers* that is not outweighed by any consumer or competitive benefits which the practice produces.” Iowa Code § 714.16(1)(n) (2007) (emphasis added). Accordingly, to be actionable under the CFA, both “deception” and “unfair practices” must be directed at “consumers.” Because the State is not a consumer, the State has not adequately alleged any unlawful practice under the CFA.

3. *The State Acts On Its Own Behalf – Not On Behalf Of Citizens – In This Action*

While the State of Iowa is not a “person” or a “consumer” under the CFA, the State could theoretically bring a CFA suit on behalf of *Medicaid beneficiaries*, if those beneficiaries paid co-pays based on AWP. However, because Iowa Medicaid beneficiaries pay only a flat co-pay, which ranges from \$1.00 to \$3.00 per prescription, *see* Iowa Admin. Code

r. 441-79.1(13)(a) (2008), they cannot have been injured by any AWP practices. Further, the Complaint makes clear that the State is not seeking to recover any damages on behalf of Medicaid beneficiaries. Throughout the Claims for Relief presented by the State, not one reference is made to the citizens or taxpayers of Iowa. Instead, each Claim for Relief specifically mentions harm done to or damages sustained by the State of Iowa. *See, e.g.*, Compl. ¶¶ 640, 642, 651, 654(b), 655, 657, 660, 661, 668-671.¹⁷

Because Iowa is not a “person” within the meaning of the CFA, and because it has not sued (and, indeed, cannot sue) on behalf of any “persons” or consumers, the State cannot maintain Count III.

D. Count IV Fails To State A Claim For Common Law Fraud

To state a claim for common law fraud, the Complaint must allege with respect to each Defendant: (1) a false representation; (2) materiality; (3) scienter; (4) intent to deceive; (5) reliance; and (6) resulting injury and damage. *Cornell*, 408 N.W.2d at 374; *see also McGough*, 526 N.W.2d at 331.

1. The Complaint Fails To Allege Any False Representation

Iowa’s fraud claim is premised on the notion that Defendants’ AWP, WACs, and other pricing data submitted to publishers must be accurate indicators of actual acquisition costs. The Complaint, however, never alleges that: (1) Defendants made any representations to the State regarding the actual or estimated transaction prices of their drugs; (2) Defendants represented, to either Iowa or third-party publishers, that their submitted pricing data represented accurate proxies for EAC; or (3) any party’s understanding of AWP was that AWP (or any other

¹⁷ While the 167-page Complaint does make two passing references to the people of Iowa, first in a heading titled “Harm to Iowa and its Citizens,” and again in one isolated reference to “taxpayers in Iowa,” Compl. p. 49 and ¶ 616, the State’s failure to make any substantive claims on behalf of Medicaid beneficiaries or Iowa taxpayers in the remainder of the Complaint makes clear that the State brings this action solely on its own behalf.

pricing data submitted to publishers) reflected EAC. Instead, the Complaint only broadly alleges that “Defendants have foiled Iowa’s attempt to reimburse providers at EAC by fraudulently misrepresenting the true prices at which they sell their drugs and reporting false and inflated prices instead.” Compl. ¶ 84. At most, the State points to a statement by First DataBank that “AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.” Compl. ¶ 98. The Complaint, however, does not allege that Defendants were the source of this third-party statement. Without any alleged false representation by Defendants regarding the meaning of AWP or any other pricing term, the Complaint fails to state a claim for fraud. Since Iowa cannot establish a false representation, it also cannot demonstrate scienter, or intent to deceive, thus preventing proof of two other elements of common law fraud.

2. *The State Cannot Establish Justifiable Reliance*

Under Iowa law, “[f]raud requires proof that [the party claiming fraud] justifiably relied on [the other party’s] representations.” *In re Marriage of Spiegel*, 553 N.W.2d 309, 317 (Iowa 1996) (citing *Beeck v. Kapalis*, 302 N.W.2d 90, 94 (Iowa 1981)). The Iowa Supreme Court has established a *subjective* standard of reliance.

[T]he test for determining whether a party to a transaction has a right to rely on representations of the other is not whether a reasonably prudent person would be justified in relying on such representations but rather, whether the complaining party, in view of his own information and intelligence, had a right to rely on the representations. This subjective standard depends not on what an ordinarily prudent person reasonably would do to protect his or her interests, but upon what the complaining party reasonably could be expected to do.

Lockard v. Carson, 287 N.W.2d 871, 878 (Iowa 1980).

While the Complaint alleges that Iowa has relied upon Defendants’ alleged misrepresentations, Compl. ¶ 660, the State cannot claim it *justifiably* relied on the alleged misrepresentations, because it knew the relationship between AWP and actual acquisition costs. *See supra* pp. 5-7, 9-13. In view of the State’s “information and intelligence,” *Lockard*,

287 N.W.2d at 878, about the inappropriateness of using AWP as a proxy for actual acquisition cost as evidenced by the Iowa legislature's 1986 directive to DHS to depart from an AWP-based reimbursement system, the State cannot truthfully allege that it justifiably relied on representations made by Defendants or on pricing data reported by third parties such as First DataBank. Without justifiable reliance, the State fails to state a claim for fraud under Iowa law.

E. Count V Fails To State A Claim For Unjust Enrichment Because The State Conferred No Benefit On Defendants

Count V is a claim in equity that Defendants have been unjustly enriched "from their unlawful acts through the increased sales of covered drugs with the greatest spread." Compl. ¶ 665. To state a claim for unjust enrichment, the State must allege that: (1) Defendants were enriched by the receipt of a benefit; (2) the enrichment was at the expense of the State; and (3) it is unjust to allow Defendants to retain the benefit. *Brown v. Kerkhoff*, 504 F. Supp. 2d 464, 543-44 (S.D. Iowa 2007).

Iowa does not sufficiently allege that it conferred a benefit on Defendants. Neither does Iowa allege that manufacturers received any overpayments because of AWP inflation. Instead, the Complaint explicitly asserts that overpayments went to pharmacies and providers. Compl. ¶¶ 57, 67. The Complaint does not allege that the pharmacies and providers passed along any overpayments to any Defendant, or that any manufacturer received payments to which it was not entitled. Thus, if anyone received a benefit from the "spread," it was the pharmacies and providers, not Defendants.

The only arguable benefit is that the State's overpayments "increased sales of [Defendants'] covered drugs with the greatest spread." Compl. ¶ 665. However, Iowa law requires a causal relationship between the benefit conferred upon a defendant and the harm sustained by a plaintiff. Damages cannot be "too remote and derivative." *Southard v. Visa U.S.A. Inc.*, No. LACV 031729, 94491, 2004 WL 3030028, at *5 (Iowa Dist. Ct. Nov. 17, 2004)

(Defs. App. Ex. S), *aff'd*, 734 N.W.2d 192 (Iowa 2007). In *Southard*, class action plaintiffs, representing Iowa citizens, sued credit card companies alleging that their “tying” of credit card and debit card services caused merchants to pay excessive and unjustified fees that merchants then passed on to the plaintiffs. *Id.* at *1. The court granted the defendants’ motion to dismiss the unjust enrichment claim, holding that where “the plaintiffs’ damages are too remote and derivative . . . [t]he plaintiffs have no cause of action under the theory of unjust enrichment.” *Id.* at *5. The relationship here between Iowa’s alleged loss and Defendants’ alleged gain is similarly attenuated. Iowa fails to provide facts demonstrating that changes in Defendants’ sales or market share are related to reported prices and not other factors such as availability of supply, individual product characteristics, quality of sales force, customer demand, etc. Without linking the State’s alleged overpayments and the alleged benefit to Defendants, Iowa fails to state a claim for unjust enrichment.

F. Iowa’s Best Price Claims Are Barred By The Filed Rate Doctrine

Iowa’s claims that certain Defendants “did not report accurate Best Prices [to CMS] for its drugs or pay correct Medicaid rebates,” causing “massive foreseeable damage to Iowa,” *see* Compl. ¶¶ 649, 651, are barred by the filed rate doctrine. That doctrine provides that rates filed and approved by a governing agency are “per se reasonable and unassailable in judicial proceedings brought by ratepayers.” *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17, 18 (2d Cir. 1994). The doctrine is not limited to rates, but extends to other regulatory decisions. *County of Stanislaus v. Pac. Gas & Elec. Co.*, 114 F.3d 858, 863-64 (9th Cir. 1997) (under the filed rate doctrine, the Economic Regulatory Administration’s approval of the volume of gas defendant imported is conclusively reasonable and not subject to plaintiffs’ challenge). Furthermore, the filed rate doctrine bars any claim that challenges a filed rate, even when the challenged rate is

alleged to be “the result of fraud committed by a defendant upon [the] rate-setting agency.” *County of Suffolk v. Long Island Power Auth.*, 154 F. Supp. 2d 380, 386 (E.D.N.Y. 2000).

Unlike AWP, the Best Prices at issue are filed with CMS, after which CMS calculates URAs for each drug, as prescribed by statute. The URAs are the basis for calculating Medicaid rebates. Thus, the State’s Best Prices claims are barred by the filed rate doctrine. Litigation over the Best Prices would “interfere[] with congressionally created federal regulatory processes.” *Town of Norwood v. New England Power Co.*, 23 F. Supp. 2d 109, 116-17 (D. Mass. 1998), *aff’d in part & remanded in part*, 202 F.3d 408 (1st Cir. 2000). The State’s request for damages under these claims would require the Court to compare the Best Prices filed with CMS with the rates that might have been filed absent the alleged fraud. The filed rate doctrine prohibits such second guessing of regulatory determinations. *Id.* at 117.

G. The State’s FUL And SMAC Claims Fail Because FULs And SMACs Are Set By CMS And Iowa, Respectively

1. FULs Are Not Set Or Reported By Defendants

By regulation, prior to 2007, FUL was to be set at 150% of the “published price” for the least costly therapeutic alternative that could be purchased in quantities of 100, plus a dispensing fee. 42 C.F.R. § 447.332(b) (2006). The State alleges that “when defendants intentionally report false and inflated WACs, AWP, and other wholesale prices to the publishing compendia, they cause the FUL to be set at a level higher than it would have been had defendants reported accurate prices in the first place.” Compl. ¶ 104. However, FULs are calculated by CMS based on what it determines is 150% of the lowest reported price.¹⁸ The

¹⁸ As explained by the DOJ in its “Brief of the United States on the Federal Upper Limit,” the “published prices” that the government uses are AWP, WAC, and Direct Prices published in the national drug pricing compendia (Red Book, Blue Book, and Medi-Span). Brief of the United States on the Federal Upper Limit, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 4413 (D. Mass. June 28, 2007).

federal statute that directed CMS to identify FUL drugs did not impose an obligation on manufacturers about which prices to report. Manufacturers neither set nor report FULs; therefore, the State's claims as to generic drugs with FULs should be dismissed.

In the Consolidated New York Counties case, this Court determined that it was not prepared to rule whether FUL drugs should be dismissed from the litigation, but instead proposed a test case limiting discovery to ten FUL drugs and then fast-tracking discovery regarding those drugs. *See* Transcript of Motion Hearing Before the Honorable Patti B. Saris, July 26, 2007. At the very least, the Court should stay discovery as to Iowa FUL drugs until a determination is made in the Consolidated New York Counties litigation.

2. *Defendants Do Not Set Or Report SMAC Prices*

The Complaint alleges that Iowa's SMAC has existed since 2001 for "certain multi-source generic and other drugs in an effort to approximate providers' EAC for those drugs." Compl. ¶ 109. Defendants neither publish Iowa SMACs nor have any control over how the SMACs are set. The Iowa Administrative Code defines SMAC as "the average wholesale acquisition cost for a drug and all equivalent products (the average price pharmacies pay to obtain drugs as *evidenced by purchase records*) adjusted by a multiplier of 1.4, plus the professional dispensing fee specified in paragraph 'g.'" Iowa Admin. Code r. 441-79.1(8)(a)(3) (2008) (emphasis added). Because SMACs are set by the State based on *actual purchase records*, and not based upon any published pricing, the allegation that Defendants inflated SMACs is unfounded. Any claims where the State reimbursed based on SMAC pricing should be dismissed from the case.

H. **Drugs With A Spread Of 30% Or Less Should Be Dismissed From The Case**

This Court has previously considered the meaning of AWP in the context of reimbursement for brand name drugs, and has rejected the theory that "defendants acted unfairly

and deceptively by having any spread between the published AWP and the true average of prices charged to providers.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 32 (D. Mass. 2007) (“Track 1 Trial”). The Court found that from at least 1990 onwards, “most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup” for brand name drugs.¹⁹ *Id.* at 40. Nor, the Court found, did payors believe that actual “spreads” were limited to the published difference between WAC and AWP: “payors were aware that there was some discounting from WAC.” *Id.* After review of the evidence, the Court adopted plaintiffs’ expert Hartman’s “yardstick” and held that brand name drugs with spreads of 30% or less were not subject to liability. *Id.* at 92, 101-02.

Iowa Medicaid’s extensive knowledge of and experience with the Medicaid system is at least as extensive as that of the third-party payors in the Track 1 Trial. While Defendants do not subscribe to Hartman’s 30% “yardstick” and continue to challenge Hartman’s methodology and conclusions, based on the Track 1 Trial decision, at a minimum, the Court should dismiss from this case any drugs where the State alleges spreads of 30% or less. Alternatively, the Court should stay any discovery as to those drugs – as it did in the Consolidated New York county cases.

III. THE FRAUD ALLEGATIONS UNDERLYING EACH COUNT ARE NOT PLEADED WITH PARTICULARITY AS REQUIRED BY FED. R. CIV. P. 8(a) AND 9(b)

Federal Rule of Civil Procedure 8(a) requires that a complaint meet the requirement of notice pleading through “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). For claims alleging fraud, however, Rule 9(b) contains a

¹⁹ To the extent such a formulaic relationship exists, it is not applicable to multi-source or generic drugs.

heightened pleading standard where the plaintiff “must state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). “The particularity requirement means that a complaint must specify the time, place, and content of an alleged false representation. Conclusory allegations and references to plans and schemes are not sufficient.” *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007) (citations and internal quotation marks omitted) (upholding trial court’s dismissal of a complaint for failure to allege fraud with particularity). When multiple defendants are sued, Rule 9(b) “requires that fraud be alleged particularly as to each defendant.” *Goebel v. Schmid Bros.*, 871 F. Supp. 68, 73 (D. Mass. 1994).

In the AWP multidistrict litigation, this Court required plaintiffs to allege

with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug Subsequent MDL decisions have added a requirement that the complaint allege a good faith estimate of an actual market price from which the spread may be calculated.

Consol. NY Counties, 2007 WL 1051642, at *14 (citations and internal quotation marks omitted).

Because fraudulent conduct is the basis for each of the State’s claims, the State must satisfy the requirements of Rule 9(b) as to each Defendant and each Count. As explained below, the Complaint’s vague and conclusory allegations do not satisfy Rule 9(b).

A. Counts I And II: Medicaid Rebate Statute And Rebate Agreement Claims

Counts I and II allege violations of the Rebate Statute and breach of the Rebate Agreement. Both Counts rely on allegations of fraudulent misrepresentations of single source and brand name innovator Best Prices submitted to CMS. This Court dismissed similar claims of fraudulent Best Prices in other AWP litigations where the plaintiff failed to provide a list of defendant-specific drugs or practices. *County of Suffolk v. Abbott Labs.*, No. 1456, Civ.A. 01-12257-PBS, 2004 WL 2387125, at *2 (D. Mass. Oct. 26, 2004) (“*Suffolk*”); *Consol. NY*

Counties, 2007 WL 1051642, at *16. The Court held that Best Prices claims “fall woefully short under Rules 8(a) and 9(b)” where the plaintiff fails to “tie[] the Best Prices claims to any particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices.” *Suffolk*, 2004 WL 2387125, at *2. “[A]bsent particularized allegations concerning each defendants’ allegedly fraudulent reporting of Best Prices for specific drugs, plaintiffs have failed to carry their burden under Rule 9(b).” *Consol. NY Counties*, 2007 WL 1051642, at *16.

Counts I and II make broad allegations that each single source and brand name innovator Defendant reported incorrect Best Prices by excluding “discounts, . . . rebates, off-invoice transactions, free samples and other inducements . . . and through abuse of the Nominal Price Exception (‘NPE’) to the Best Price Reporting requirements.” Compl. ¶ 636. With the exception of a limited number of drugs and Defendants identified in Section X of the Complaint, the State does not properly allege fraudulent Best Prices. The Complaint appears to allege damages with respect to every single source or brand name innovator drug that was purchased by the State, without specifically identifying these drugs.²⁰ These allegations do not satisfy Rule 9(b)’s requirement that the Complaint tie every allegation of fraud to each Defendant with reference to a specific drug or practice for which the State seeks damages. Even if the Complaint is limited only to the drugs in Exhibit B, the State still does not allege for which drugs fraudulent Best Prices were submitted, which Defendants submitted the fraudulent Best Prices, or what the “actual” Best Prices should have been.

The only attempt the State makes to provide details of fraudulent Best Prices practices is in Exhibit F to the Complaint, which contains a January 31, 2007 Senate Finance

²⁰ Paragraph 18 of the Complaint alleges that the specific drugs at issue in this litigation are identified in Exhibits B-1 through B-33. However, those Exhibits do not reference Best Prices.

Committee (“Committee”) study regarding the use of the NPE under the Medicaid Drug Rebate Program. The State alleges that twelve of the nineteen companies studied were “misusing” the NPE. The allegations of “misuse” do not satisfy the pleading requirements under Rules 8(a) and 9(b). Nowhere in the Committee study does it list which twelve companies were misusing the NPE, which specific drugs were investigated by the Committee, or whether the misuse of the NPE in fact resulted in lower rebates to the states. In the *Consol. NY Counties* case, this Court deemed a similar Committee investigation to be insufficient evidence of Best Prices violations. 2007 WL 1051642, at *16. Exhibit F does not satisfy the State’s Rule 9(b) burden to assert particularized allegations concerning each Defendant’s allegedly fraudulent reporting of Best Prices for specific drugs.

B. Counts III And IV: Consumer Fraud Act And Common Law Fraud Claims

1. Best Prices Allegations

Counts III and IV assert claims under the Iowa Consumer Fraud Act and common law fraud for, *inter alia*, alleged submissions of false, misleading, and fraudulent Best Prices. Compl. ¶¶ 654, 659, 660, 662. As these allegations are based on fraud, the pleadings must satisfy Rule 9(b). As discussed above, the Best Prices allegations make only broad statements regarding Defendants’ misreporting of Best Prices. Neither Count III nor Count IV charges a particular Defendant by name or specifies any drug. Compl. ¶¶ 652-662. With the exception of limited drugs and Defendants identified in Section X, the Complaint fails to tie the Best Prices fraud claims to any particular drugs, discounts, or other company-specific practices. Since the Complaint does not allege Best Prices claims with the particularity required under the Federal Rules, Counts III and IV must fail with respect to Best Prices.

2. WAC And “WAC Equivalent” Allegations

The State’s conclusory allegations as to WAC and “WAC equivalents (such as Direct Prices, Book Prices, Wholesale Net Prices, Catalog Prices, or List Prices),” Compl. ¶ 88, are insufficient under Rule 9(b). Without any particularity, the State merely alleges that Defendants’ WACs and “WAC equivalents” “are uniformly false and inflated.” Compl. ¶ 88. The State fails to provide specific allegations as to any particular Defendant or the amount of inflation for specific drugs. The Complaint alleges that “some” Defendants submitted false WACs or “WAC equivalents” to publishers that then applied a “standard 1.2 or 1.25 mark-up.” Compl. ¶¶ 95, 97. The State does not specify which of these Defendants’ WACs or “WAC equivalents” were “marked-up,” for which specific drugs the State is alleging inflation, or what the WACs or “WAC equivalents” should have been.²¹ Without specific allegations of fraudulent WACs as to each Defendant or reference to specific drugs at issue, the State’s WAC and “WAC equivalent” claims fail under Rule 9(b).

3. SMAC Allegations

The State alleges false prices with respect to the SMAC pricing benchmark. The State admits that SMAC pricing has existed only since 2001 and, even then, only for “certain multi-source generic and other drugs.” Compl. ¶ 109. The State’s SMAC allegations fail to satisfy Rule 9(b) for the simple reason that neither the Complaint nor the Exhibits attempt to specify which Defendants and which drugs were reimbursed under the SMAC program. Similar to the *Suffolk* case, Iowa’s SMAC claims fail under Rule 9(b) because the State does not tie the SMAC claims “to any particular drugs, discounts or other company-specific practices which

²¹ Exhibit C to the Complaint allegedly identifies drugs for which the WAC/AWP spread increased from 20% to 25%. However, Exhibit C provides no WAC pricing information and, in fact, includes manufacturers that are not parties to this lawsuit. Exhibit C does not satisfy Rule 9(b) because the State does not explain which Defendants’ WACs are at issue, specify which drugs are at issue, provide any WAC pricing data, or provide any information regarding the spread between WACs and actual transaction prices.

would support an inference of misrepresenting Best Prices,” or in this case, SMAC prices.

Suffolk, 2004 WL 2387125, at *2.

C. Count V: Unjust Enrichment

1. *Unjust Enrichment Claims Fail Under Rule 9(b)*

Count V does not specify an independent basis for its claims; rather, it relies on the allegations in the preceding paragraphs of the Complaint. Compl. ¶¶ 663-666. Throughout the Complaint, each of the State’s allegations is premised on Defendants’ intentional and fraudulent misrepresentations. Unjust enrichment claims premised entirely on fraudulent conduct are subject to Rule 9(b) particularity requirements. *Consol. NY Counties*, 2007 WL 1051642, at *10; *see Daly v. Castro Llanes*, 30 F. Supp. 2d 407, 414 (S.D.N.Y. 1998). Because the State’s unjust enrichment claims rely on allegations of fraudulent conduct, the Complaint must be pleaded in accordance with the particularity requirements of Rule 9(b).

2. *Unjust Enrichment Claims Also Fail Under Rule 8(a)*

As in the *Consol. NY Counties* case, Iowa’s unjust enrichment claims as they relate to Best Prices, WAC/“WAC equivalents,” and SMAC pricing also fail to meet the notice pleading requirement of Fed. R. Civ. P. 8(a). 2007 WL 1051642, at *10. In *Consol. NY Counties*, this Court dismissed unjust enrichment claims related to Best Prices because “with respect to most defendants, the counties h[ad] ‘not tied the Best Prices claims to any particular drugs, discounts or other company specific practices which would support an inference of misrepresenting Best Prices.’” *Id.* (quoting *Suffolk*, 2004 WL 2387125, at *2-*3). The Counties’ use of unproven allegations made by Congress or law enforcement agencies was insufficient. *Id.*

Similarly, Iowa’s unjust enrichment claims regarding Best Prices, WAC/“WAC equivalents,” and SMAC pricing fail for not providing Defendants minimal facts regarding

fraudulent or false pricing for specific drugs, or information showing “a company-wide scheme to misstate” these pricing benchmarks. *Id.* (citation omitted).

IV. AT THE VERY LEAST, THE COURT SHOULD LIMIT THE DAMAGES PERIOD TO 1992 THROUGH AUGUST 1997

Assuming this Court does not find the public record concerning Iowa Medicaid’s knowledge and the other legal arguments dispositive, the extent of the damages period for this case should be 1992 through August 1997. The Complaint only contains damages data going back to 1992. *See* Compl. Ex. A. And although Complaint Exhibit A contains damages data through 2005, the absolute outer boundary for damages should be not 2005, but 1997.

According to this Court’s June 2007 opinion, the very latest the State of Iowa could have been on notice of the allegations that form the basis of the lawsuit would have been with the passage of the Balanced Budget Act in August 1997. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 79.²² Iowa Medicaid cannot possibly claim to have been defrauded after that time. Because of its full knowledge of the nature of AWP, the State cannot claim that there were false representations on the part of manufacturers, or that the State justifiably relied on the manufacturers’ representations after this time. Finally, the State was empowered to change the Medicaid reimbursement rate if it so desired,²³ and nothing prevented a change to a non-AWP-based drug reimbursement methodology.

²² This is when the Court found that Blue Cross Blue Shield of Massachusetts (“BCBSMA”) should have been aware that AWP was not a proxy for actual acquisition cost. State Medicaid programs should have known even more than BCBSMA with respect to Medicaid reimbursement. Indeed, it is clear that Iowa Medicaid was aware that AWP did not reflect actual transaction prices sometime before 1986. *See supra* pp. 5-7.

²³ In fact, Iowa did change its reimbursement formula during the period at issue. For example, in 2003, the Iowa Medicaid regulations were amended to change reimbursement from AWP minus 10% to the current level of AWP minus 12%. *See* Iowa Admin. Code r. 441-79.1(8)(a), (b) (2004) (Defs. App. Ex. F). *But see* Compl. ¶ 78 (“From 1991 to 2005, Iowa defined EAC as AWP-10%.”).

CONCLUSION

For the foregoing reasons, Defendants respectfully urge the Court to dismiss Iowa's Complaint in its entirety.

<p>Dated: February 20, 2008</p>	<p><u>/s/ J. Andrew Jackson</u> J. Andrew Jackson Tina D. Reynolds Shamir Patel DICKSTEIN SHAPIRO LLP 1825 Eye Street NW Washington, DC 20006 Telephone: (202) 420-2200 Facsimile: (202) 420-2201</p> <p><u>/s/ Peter E. Gelhaar</u> Peter E. Gelhaar (BBO #188310) DONNELLY, CONROY & GELHAAR, LLP One Beacon Street, 33rd Floor Boston, MA 02108 Telephone: (617) 720-2880 Facsimile: (617) 720-3554</p> <p>Counsel for Defendants Baxter Healthcare Corporation and Baxter International Inc. and on behalf of:</p> <p>Abbott Laboratories, Inc. Agouron Pharmaceuticals, Inc. Alpharma, Inc. ALZA Corporation Amgen Inc. AstraZeneca LP AstraZeneca Pharmaceuticals, LP Aventis Behring LLC (n/k/a ZLB Behring LLC) Aventis Pharmaceuticals, Inc. Barr Laboratories, Inc. Baxter Healthcare Corporation Baxter International Inc. Bayer Corporation Bayer Pharmaceuticals Corporation Ben Venue Laboratories, Inc. Boehringer Ingelheim Corporation Boehringer Ingelheim Pharmaceuticals, Inc. Bristol-Myers Squibb Company Chiron Corporation Dey, Inc. Dey, L.P. Eli Lilly and Company Endo Pharmaceuticals Inc. Ethex Corporation Ethicon, Inc.</p>
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	<p> Forest Laboratories Forest Pharmaceuticals, Inc. Geneva Pharmaceuticals, Inc. Greenstone LTD. Hoffmann-La Roche Inc. Immunex Corporation Ivax Corp. Ivax Pharmaceuticals, Inc. Janssen L.P. Johnson & Johnson King Pharmaceuticals, Inc. King Research and Development McNeil-PPC, Inc. MedImmune, Inc. Merck & Co., Inc. Monarch Pharmaceuticals, Inc. Mylan Laboratories Inc. Mylan Pharmaceuticals Inc. Novartis Pharmaceuticals Corporation Novopharm USA, Inc. Oncology Therapeutics Network Corporation Ortho-Biotech Products, L.P. Ortho-McNeil Pharmaceutical, Inc. Par Pharmaceutical Companies, Inc. Par Pharmaceutical, Inc. Pfizer Inc. Pharmacia Corporation Purdue Pharma L.P. Purepac Pharmaceutical, Co. Roche Laboratories Inc. Roxane Laboratories, Inc. (N/K/A Boehringer Ingelheim Roxane, Inc.) Sandoz Inc. Schering Corporation Schering-Plough Corp. Sicor, Inc. SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") TAP Pharmaceutical Products Inc. Teva Pharmaceuticals USA, Inc. UDL Laboratories, Inc. Warrick Pharmaceuticals Corporation Watson Pharma, Inc. Watson Pharmaceuticals, Inc. Wyeth Wyeth Pharmaceuticals, Inc. </p>
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CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, caused a true and correct copy of the foregoing, MEMORANDUM OF LAW IN SUPPORT OF CERTAIN DEFENDANTS' MOTION TO DISMISS THE COMPLAINT, to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, on February 20, 2008, for posting and notification to all parties.

/s/ Shamir Patel

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